



California Drug Safety Notification



Notification Name

U. S. FDA Warns Consumers That Acetaminophen Has Been Associated With Risk of Serious Skin Reactions

Notification Date	Notification Warning	Notification Reason
08/01/13	The U.S. Food and Drug Administration (FDA) is warning consumers and health care professionals that acetaminophen has been associated with serious skin reactions including Stevens-Johnson Syndrome (SJS), toxic epidermal necrolysis (TEN), and acute generalized exanthematous pustulosis (AGEP), which can be fatal.	<p><i>Acetaminophen is a common active ingredient in prescription and over-the-counter pain relievers and fever reducers. Patients who develop a skin reaction while using acetaminophen should stop using it and contact their doctor. Physicians should be aware of this rare risk.</i></p> <p><i>The FDA will require a warning label to be applied to prescription drugs containing acetaminophen addressing the risk of serious skin reactions and ask manufacturers of over-the-counter products to do the same.</i></p>

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm363519.htm?source=govdelivery>